## REMARKS

### I. Status Summary

Claims 17-48 are pending in the present application. Claims 20-28, 30, and 33-48 have been *sua sponte* withdrawn by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 17-19, 29, 31, and 32 have been rejected.

Claims 33-48 have been canceled. Applicants hereby reserve the right to file one or more divisional and/or continuation patent application(s) with claims directed to the canceled subject matter. No new matter has been added. Therefore, upon entry of Amendment A, claims 17-19, 29, 31, and 32 will be pending in the subject application.

Reconsideration of the application as amended and further in view of the remarks set forth herein below is respectfully requested.

### II. Response to Rejections under 35 U.S.C. § 102(b) over Kaminski

Claims 17-19, 29 and 31 have been rejected under 35 U.S.C. 102(b) upon the contention that the claims are anticipated by U.S. Patent No. 5,453,428 to Kaminski (hereinafter "Kaminski"). In particular, the Patent Office contends that Kaminski teaches the treatment of Alzheimer's disease with a first compound and other compounds. The Patent Office further contends that pentamidine is disclosed by Kaminski at column 4, line 31. See Official Action, page 2.

After careful consideration of the rejection and the Patent Office's reasons therefore, applicants traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that to provide a basis for a rejection under 35 U.S.C. § 102(b) the cited art must teach each and every element of the claim. See *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); and Manual of Patent Examining Procedure (hereinafter "MPEP") § 2131.

Applicants respectfully submit that Kaminski is generally directed to the treatment of apathy-amotivation syndrome, and of related symptoms in Alzheimer's disease and other conditions, by treatment with a histamine $H_2$ antagonist. See Kaminski, column 2, lines 25-31. Kaminski further describes that the histamine $H_2$ antagonist can be co-administered with another compound known to be useful in the treatment of the other symptoms of the various neuropsychiatric disorders. See Kaminski, column 3, lines 31-34. Kaminski then describes a number of specific diseases one at a time, along with the specific symptoms associated with each disease and the compounds or types of compounds that could be used as additional compounds to treat those symptoms in each particular disease.

For example, Kaminski recites a number of symptoms associated with Alzheimer's disease, including: deterioration of memory capacity, apathy, delusions, hallucinations, and irritability. See Kaminski, column 3, lines 35-36 and lines 45-46. Kaminski also teaches various compounds and classes of compounds (e.g., psychostimulants, antidepressants, acetyl-choline precursors, muscarinic agonists, acetylcholinesterase inhibitors, cholinomimetics, and notropics) that can be used to treat those symptoms of Alzheimer's disease. See Kaminski, column 3, lines 49-59. Applicants respectfully submit that one of skill in the art after review of Kaminski, would understand that formulations for treating Alzheimer's disease could include a histamine $H_2$ antagonist and one or more of the compounds or types of compounds listed in column 3, lines 49-59. Kaminski does not specifically teach or suggest the use of pentamidine, or any other amidine, in the treatment of Alzheimer's disease.

Applicants respectfully submit that, at best, Kaminski only suggests the use of pentamidine in the treatment of HIV infection or AIDS. See Kaminski, column 4, lines 8-31. In particular, pentamidine is listed as a "Miscellaneous" compound for treating HIV/AIDS.

Accordingly, applicants respectfully submit that Kaminski does not teach each and every element of claim 17. Claims 18, 19, 29, and 31 each depend

from claim 17, and therefore, contain each and every element of claim 17. Thus, applicants respectfully submit that claims 18, 19, 29, and 31 have also been distinguished from Kaminski. Applicants respectfully request that the rejection of claims 17-19, 29, and 31 under 35 U.S.C. § 102(b) over Kaminski be withdrawn and that claims 17-19, 29, and 31 be allowed at this time.

In addition, as Kaminski does not appear to disclose the use of an amidine compound in the treatment of Alzheimer's disease, applicants respectfully request the rejoinder of claims 20-28 and 30, which are directed to the use of additional species of amidine compounds in the treatment of Alzheimer's disease, at this time.

III. Response to the Rejection under 35 U.S.C § 112, first paragraph

The Patent Office has rejected claim 32 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Patent Office alleges that the applicants provide no standard by which to determine prophylaxis. See Official Action, page 2.

After careful consideration of the rejection and the Patent Office's remarks therefore, applicants respectfully traverse the rejection and offer the following comments.

Initially, applicants respectfully submit that the burden rests upon the Patent Office to establish a *prima facie* case of a failure to comply with 35 U.S.C. § 112, first paragraph. See *In re Marzocchi*, 58 C.C.P.A. 1069, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971). There are many factors to be considered when making the determination as to whether an application has met the requirements for enablement under 35 U.S.C. § 112, first paragraph, these factors including: (a) the breadth of the claims, (b) the nature of the invention, (c) the state of the prior art, (d) the level of ordinary skill in the art, (e) the level of predictability in the art, (f) the amount of direction provided by the inventor, (g) the existence of working examples, and (h) the quantity of experimentation needed to make or use the invention based on the content of

the disclosure. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) and MPEP § 2164.01(a).

Further, not everything necessary to practice the invention need be disclosed. See MPEP § 2164.08, citing *In re Buchner*, 929 F. 2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Id., citing *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The instant application describes a number of "active compounds" and salts of active compounds that have high affinity for the imidazoline $I_2$ receptor. See Instant Specification, pages 6-14. The instant application further states that the amount of active compound administered will depend on various factors, including the subject being treated and the severity of the affliction, and provides representative dosage ranges. See Instant Specification, page 15, lines 18-23.

Applicants respectfully submit that a person of ordinary skill in the art would understand that preventing a disease in a subject that is predisposed to (or otherwise at risk of developing) the disease would be classified as prophylactic treatment. In particular, a prophylactic treatment can be construed as one in which a subject predisposed to the disease does not become diagnosed with the disease. It is further believed that one of ordinary skill in the art would understand, after review of the present specification, that the compounds described by the application can be administered in subjects predisposed to the development of Alzheimer's disease at various dosages, and that these subjects can be followed for a period of time to determine whether treatment with the subject compounds reduces the subjects' likelihood of developing and actually being diagnosed with Alzheimer's disease. Applicants respectfully submit that such testing does not involve undue experimentation (i.e., experimentation that could be classified as being beyond the scope of that normally engaged in by those of skill in the pertinent art).

Thus, applicants respectfully submit that a specific "standard" by which to determine prophylaxis is not needed by one of ordinary skill in the art to understand how to make and use the presently claimed subject matter.

Accordingly, applicants respectfully submit that the present rejection of claim 32 under 35 U.S.C. § 112, first paragraph, is improper. Applicant respectfully request that the present rejection of claim 32 under 35 U.S.C. § 112, first paragraph, be withdrawn and request that claim 32 be allowed at this time.

## IV. Response to the Rejection under 35 U.S.C. § 101

The Patent Office has rejected claim 32 under 35 U.S.C. § 101 as allegedly lacking patentable utility. The Patent Office contends that the applicants do not provide evidence of prevention or an experimental regime for determining such. See Official Action, page 3.

After careful consideration of the rejection and the Patent Office's remarks therefore, applicants respectfully traverse the rejection and offer the following comments.

Initially, applicants respectfully submit that, generally, applicants' assertion of utility creates a presumption of utility that will be sufficient to satisfy the requirement of 35 U.S.C. § 101. See *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977); and MPEP § 2107.02. Moreover, an assertion of utility is credible unless (a) the logic underlying the assertion is seriously flawed or (b) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. See MPEP § 2107.02. Thus, the Patent Office bears the burden of making a *prima facie* showing that the claimed invention lacks utility, and to provide sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. Id, citing *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ

664,666 (CCPA 1975). In particular, the Patent Office must establish that it is more likely than not that one of ordinary skill in the art would doubt an asserted ulitity. Id.

Applicants respectfully submit that the Patent Office has failed to make a *prima facie* showing that one of ordinary skill in the art would not believe that the presently disclosed compounds could be used in the prophylaxis of Alzheimer's disease. Rather, the Patent Office merely contends that the applicants have not provided a direct proof of such a utility or a specific experimental regime for determining the ability of the compounds to effect prophylaxis.

Accordingly, applicants respectfully submit that the Patent Office has not met their burden of proof in challenging the claimed use of the presently disclosed compounds.

Further, specifically with regard to therapeutic or pharmacological utility, including prophylactic utility, applicants note that, inventions providing any immediate benefit to the public have been found to satisfy 35 U.S.C. § 101, and, further, that the identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides such "immediate benefit to the public." See MPEP § 2107.01, citing *Nelson v. Bowler*, 626 F2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

Applicants respectfully submit that the instant application describes that expression of $I_2$ binding sites is upregulated in patients with Alzheimer's disease (see Instant Specification, page 2, lines 18-20). The instant application also provides experimental evidence that the presently disclosed "active compounds" have $I_2$ binding ability. See, for example, Instant Specification, page 21, line 20 to page 22, line 19, and Tables 1-3. Accordingly, applicants respectfully submit that the identification of a relevant pharmacological activity has been made to support the asserted utility of the presently disclosed compounds as prophylactic compositions for use in preventing Alzheimer's disease.

Applicants respectfully request that the rejection of claim 32 under 35 U.S.C. § 101 be withdrawn and ask that claim 32 be allowed at this time.

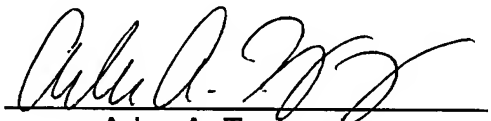
## CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

## DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any additional fees associated with the filing of this correspondence to Deposit Account No. **50-0426**.

Respectfully submitted,
JENKINS, WILSON, TAYLOR & HUNT P.A.

Date: May 30, 2007 By: 

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